



1279 '99 MM 23 P2:14

March 15, 1999

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204



Dear Sirs:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement within the last thirty days under the Sundown Herbals brand name bearing the following statement(s) on the label and/or in the labeling:

Echinacea & Goldenseal Complex: For healthy immune function. Echinacea helps support healthy immune function and promotes general well-being during the winter months. Goldenseal helps maintain healthy respiratory function. Vitamin C is an essential water-soluble vitamin that needs to be replaced in your system regularly. It is also a powerful antioxidant that provides protection for healthy cells and body systems. To further promote healthy immune function, take this product with Sundown Zinc Lozenges and Sundown Elderberry. Zinc is an important nutrient that helps to regulate the production of cells in the body's immune system. Elderberry contains numerous beneficial compounds that may help support healthy immune function and promote general well-being.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

Vice President of Regulatory Affairs

and Assistant General Counsel

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Enclosure